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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,463	06/12/2001	Michel Pagniez	01076	2261
23338	7590	10/23/2003	EXAMINER	
DENNISON, SCHULTZ & DOUGHERTY 1745 JEFFERSON DAVIS HIGHWAY ARLINGTON, VA 22202			HELMER, GEORGIA L	
ART UNIT	PAPER NUMBER			
1638	/ /			

DATE MAILED: 10/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application N .</b>	<b>Applicant(s)</b>
	09/821,463	PAGNIEZ ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Georgia L. Helmer	1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 25 June 2003.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 16-27,30-32,36 and 37 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 16-27,30-32,36 and 37 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_

DETAILED ACTION

***Status of the Claims & Restriction-Election***

1. The Office acknowledges Applicant's response dated 25 June 2003, paper No.10, to the Restriction Requirement filed 25 March 2003. Applicant has elected Groups I, claims 16-27 and 30-35, with traverse. Applicant traverses, stating primarily that in the instant case the special technical feature is the transformation of plant cells with Agrobacterium rhizogenes and selecting the transformants that express an hydrogen peroxide producing protein, and that the prior art cited by Examiner, WO 94/13790, does not teach this. Applicant's traversal has been considered and is unpersuasive because WO 94/13790 clearly teaches transformation with Agrobacterium tumefaciens and Agrobacterium rhizogenes (page 8, lines 15-20). Applicant has cancelled claims 33-35, and added claims 36 and 37. Claims 16-27, 30-32 and 36-37 are pending, and are examined in the instant action.

***Information Disclosure Statement***

2. An initialed and dated copy of Applicant's IDS form 1449, dated 9 April 2001, is attached to the instant Office action.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1638

4. Claims 16-27, 30-32 and 36-37 are rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. In claim 16, this claim is written in the alternative, so that the claim can have at least two different meanings. Also, it is unclear how the parts of the claim relate to one another. Is it part (a1) or parts (a2) through (d)?

This is ambiguous and needs to be clarified.

- In 16 (a1) line 2, "gene" is unclear because a "gene" implies a DNA sequence that exists in nature and includes coding and noncoding regions, as well as all regulatory sequences associated with expression. Since this does not appear to be Applicant's intention, more definite language is suggested. Or Applicant may recite the various components of the "gene" desired. All recitations of "gene" are also rejected.
- line 3, "in a context allowing its expression" is unclear; how does a context allow? All subsequent recitations of this language are also rejected. Also, "its" lacks antecedent basis; what is "it"?
- In 16 (b), it is unclear whether both the gene encoding the hydrogen peroxide producing protein or the gene encoding the protein of interest, or both, is selected by a peroxidase-based colorimetric test. Also, in what sense is the colorimetric test peroxidase-based?

- An essential step is missing from claims 16. (b) recites selecting transformants, and (c) recites regenerating the plants from the roots. In 16, (c), lines 2-3, "what does "the plantlets obtained by a peroxidase-based colorimetric test" mean? How you produce plants from a chemical test?
- In 16(c), line 1, "the plants" lacks antecedent basis; "the roots" lacks antecedent basis. What does "plantlets obtained by a peroxidase-based colorimetric test" mean?
- In 16(d), line 1, "phenotype" is indefinite. What phenotype is used the in "sorting"? The only phenotype recited in this claim is that of h<sub>2</sub>o<sub>2</sub> production.
- Claim 16 is an incomplete method claim, because the desired product is not produced by the final step.

In claim 18, "wherein the colorimetric test in step (b) is carried out on a liquid medium for incubation after removing the Agrobacterium" is unclear. What is the relationship of the liquid medium to anything else? "After removing the Agrobacterium" from what?

In claim 19, "the transformed explants" lacks antecedent basis. "a blot left by" is unclear. How does the blot relate to the explants? A blot can be made with water and nothing else. Is this what is intended?

In claim 20 and 21, "substrate" is unclear. What substrate, from where, for what purpose?

In claim 23, "a late stage of development" of what?

In claim 25, what are “floral scrape cells”?

Clarification/correction is required.

***Claim Rejections - 35 USC § 112 -Enablement***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 16-27, 30-32 and 36-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

8. The enablement issues are “any plant”, “Agrobacterium rhizogenes containing a vector”, “a protein producing hydrogen peroxide”, “sorting according to phenotype”, the broad scope of “proteins conferring resistance to disease caused by an organisms selected from the group consisting of fungi , bacteria, arthropods and nematodes” or “to any pathogenic agent”, “any protein of agronomic or industrial interest”.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)):

*Nature of the invention.* The claims are drawn to a method for obtaining transgenic plants, comprising transforming plant cells with Agrobacterium rhizogenes

containing a vector varying a gene encoding a protein producing hydrogen peroxide, and a protein of interest, selecting transformants which express the hydrogen peroxide producing protein using a peroxidase-based colorimetric test, regenerating plants from roots selected and sorting according to phenotype and allowing selection of plants containing only the transgenic and not the Agrobacterium rhizogenes T-DNA, where the protein of interest is an endochitinase, where the protein of interest confers resistance to disease caused by an organism selected from the group consisting of fungi, bacteria, arthropods and nematodes, or any pathogenic agents, where the protein of interest is a protein of agronomic or industrial interest.

Re "any plant",

- The state of the art is such that one of skill in the art can readily make Agrobacterium comprising various DNA constructs, and coculture plants, plant parts and propagules with the Agrobacterium. However, successful transformation has specific requirements (Hansen et. al. 1999) which include an efficient DNA delivery system. The natural host range of Agrobacterium as a DNA delivery system is limited (Cley & DeLay reference), and not all plants are susceptible to Agrobacterium. Applicant claims all plants but teaches only dicots. Neither the prior art nor Applicant teaches how to transform plants not susceptible to Agrobacterium with an Agrobacterium. Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a

virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden.

Re: "a protein producing hydrogen peroxide",

- the state of the art is such that proteins catalyze reactions between appropriate substrates to produce products, leaving the protein (enzyme) behind unchanged. The only way the protein, in and of itself, could produce a product would be for the protein to be degraded into simpler components. The proteins must have appropriate substrates into order to produce hydrogen peroxide. Neither the prior art nor Applicant teaches how to produce hydrogen peroxide (as a product of a enzymatic reaction) without any substrates for the enzyme catalysis. Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden.

Re "transforming with Agrobacterium rhizogenes containing a vector" the state of the art is such that transformation with Agrobacterium rhizogenes has to contain a T-DNA in order for transformation to occur; the T-DNA can be T-DNA of a resident at T-DNA, or other T-DNA. Neither the prior art nor Applicant teaches how to

transform plants with Agrobacterium that does not contain a T-DNA. Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden.

Re: transforming with Agrobacterium rhizogenes containing a vector" to obtain transgenic plants

- the state of the art is that in order for Agrobacterium rhizogenes to transfer a gene of a vector to transgenic plants, that vector containing the gene must be flanked by appropriate T-DNA sequences. Otherwise the "gene" stays with the Agrobacterium. Neither the prior art nor Applicant teaches how to transfer "genes" to a plants using Agrobacterium unless the "genes" are flanked by appropriate T-DNA sequences. Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden.

Re: "sorting according to phenotype"

- the state of the art is that in order for one to sort according to phenotype, the phenotype(s) must be defined and specified, and related to the desired product. A myriad of phenotypes exist, and a multitudes of ways to "sort according to phenotype" abound. Applicant has provided no guidance on

how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden.

Re: protein of interest conferring resistance to disease caused by an organism selected from the group consisting of fungi, bacteria, arthropods and nematodes, or any pathogenic agents, and where the protein of interest is of agronomic or industrial interest. The group consisting "resistance of fungi, bacteria, arthropods and nematodes, or any pathogenic agents, and where the protein of interest is of agronomic or industrial interest" are not taught, rather this a listing and does not comprise adequate guidance.

In view of the breadth of the claims (any cell, any plant, any vector, any protein producing hydrogen peroxide, any phenotype, disease caused by an organisms selected from the group consisting of any fungi , any bacteria, any arthropods and any nematode, any pathogenic agent, "any protein of any agronomic or any industrial interest) the lack of guidance in the specification, and the unpredictability in the art, undue trial and error experimentations would be required to enable the invention as commensurate in scope with the claims.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 16, 19, 24, 25, 30, 32 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson, et. al., A disarmed binary vector from Agrobacterium tumefaciens functions in Agrobacterium rhizogenes, Plant Mol. Biology, vol 6, pages 403-415, 1986, in view of Zhang, et. al., Germin-like oxalate oxidase, a hydrogen peroxide producing enzyme, accumulates in barley attacked by the powdery mildew fungus, The Plant Journal, vol. 8, pages 139-145, 1995. and applicant's admitted prior art (specification p.1, lines 12-22).

Simpson teaches a method of transforming plants comprising transforming tobacco cells (p. 411, column 2 last full ¶) with Agrobacterium rhizogenes (p. 409, column 1 last ¶) containing a vector carrying a gene, selecting transformants (p. 409-table 2) which contain and express the gene, sorting according to phenotype to obtain transgenic plants containing only the transgenic and not the Agrobacterium rhizogenes specific T-DNA (p 411, column 2 last full ¶). Simpson also teaches inoculation of hypocotyls (p. 408, column 1, 1<sup>st</sup> full ¶), expressing and purifying the protein of interest (p. 409, table 2).

Simpson does not teach a gene encoding a hydrogen peroxide producing enzyme, the use of a peroxidase based color test, the color test being carried out on a blot and the protein of interest conferring resistance to disease caused by an organisms selected from the group consisting of any fungi , any bacteria, any arthropods and any nematode, or any pathogenic agent.

Zhang teaches a protein producing hydrogen peroxide (summary. p. 139), the use of a peroxidase-based colorimetric test to measure hydrogen peroxide (p. 144, column 1, "oxalate oxidase assay"), where the color test is carried out on a blot (p. 144, column 1) and a protein conferring resistance to fungal disease (title and summary, 139). Given the indefiniteness of the terms plants, plantlets and roots in the claims (see especially 112-2 above discussion of Claim 16) these terms are given no patentable weight.

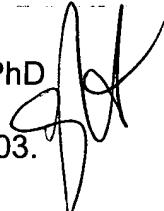
It would have been obvious to one of skill in the art, at the time of the invention was made, to utilize the gene and method of Zhang in the method of Simpson. Substituting for the kanamycin resistance gene of Simpson, the hydrogen peroxide producing protein of Zhang , would be motivated by the known desirability (specification p.1, lines 12-22) of using genes other than antibiotic resistance for selection of transgenic plants, with a reasonable expectation of success.

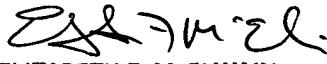
***Remarks***

11. No claims are allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia Helmer, PhD  
Patent Examiner  
September 25, 2003.  


  
ELIZABETH F. McELWAIN  
PRIMARY EXAMINER  
GROUP 1600